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1/18/07*



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

JAN 16 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

WARNING LETTER

## VIA FEDERAL EXPRESS {AND FACSIMILE}

Mr. Steve Stecklein  
Power Products, Inc.-Splintek  
3325 Wyoming Street  
Kansas City, Missouri 64111

Dear Mr. Stecklein:

The Food and Drug Administration (FDA) has learned that your firm is marketing the Sleep Right® Adjustable Night Guard in the United States (U.S.) for over the counter use to protect teeth from clenching and grinding, and for use by children 12 – 18 years old, without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Under section 201(h) of the Act, the Sleep Right® Adjustable Night Guard is a device because it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body, 21 U.S.C. 321(h). The Act requires that manufacturers of devices that are not exempt obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that new devices are shown to be both safe and effective or substantially equivalent to other devices already legally marketed in this country for which approval is not required.

A review of our records reveals that you have obtained marketing clearance (K022809) for the Right® Adjustable Night Guard for prescription use only, and for patients 18 years of age or older. However, you have not obtained marketing approval or clearance before you began offering your product for over the counter use and for use by children 12 – 18 years old, which is a violation of the law. Specifically, Sleep Right® Adjustable Night Guard is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). The device is also misbranded under section 502(o) of the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the

**EXHIBIT B**

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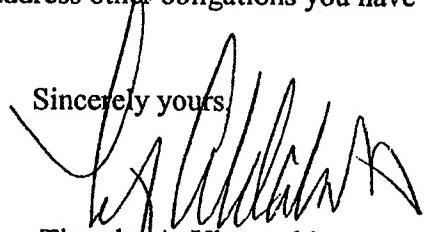
Act, 21 U.S.C. 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at <http://www.fda.gov/cdrh/devadvice/3122.html>. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please let this office know in writing what steps you have taken to correct the problem within fifteen (15) working days from the date you received this letter. We also ask that you explain how you plan to prevent this from happening again. If you need more time, please let us know why and when you expect to complete your correction. Please direct your response or any questions you may have to: Mr. Ronald L. Swann, Chief, HFZ-331, 9200 Corporate Boulevard, Rockville, Maryland, 20850. If you have any questions about the content of this letter please contact: Mr. Swann at (office) 240-276-0115 or (fax) 240-276-0114.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of devices. This letter pertains only to the issue of premarket review for your device and does not necessarily address other obligations you have under the law.

Sincerely yours,

  
Timothy A. Ulatowski  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health

## Results of Warning Letters Search

Company Name	Date Warning Letter Issued	Issuing Office	Subject	File	Response Posted
Power Products, Inc.-Splintek	1/16/07	Center for Devices and Radiological Health	Premarket Approval/Adulterated	[PDF] [HTML]	No

 [Warning Letters](#)

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Last Updated on 4/13/2007